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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/521,948	01/23/2006	Zaihui Zhang	540057.418USPC	6733

500 7590 11/28/2008
SEED INTELLECTUAL PROPERTY LAW GROUP PLLC
701 FIFTH AVE
SUITE 5400
SEATTLE, WA 98104

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT	PAPER NUMBER
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1626

MAIL DATE	DELIVERY MODE
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11/28/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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Office Action Summary	Application No. 10/521,948	Applicant(s) ZHANG ET AL.	
	Examiner Laura L. Stockton	Art Unit 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 August 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24, 27, 29-31, 34-37, 39-52 and 77-89 is/are pending in the application.
- 4a) Of the above claim(s) 30, 31, 34-37, 39-52 and 83-89 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24, 27, 29 and 77-82 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-24, 27, 29-31, 34-37, 39-52 and 77-89 are pending in the application.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-24, 27, 29 and 77-82) in the reply filed on August 22, 2008 is acknowledged. The traversal is on the ground(s) that formula (1) was incorrectly designated as formula (I). This is not found persuasive because the lack of unity would still exist as stated in the Restriction requirement. Therefore, all designations of formula (I) in the Restriction requirement should be formula (1).

The requirement is still deemed proper and is therefore made FINAL.

Claims 30, 31, 34-37, 39-52 and 83-89 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on August 22, 2008.

Information Disclosure Statement

The Examiner has considered the Information Disclosure Statements filed on January 23, 2006 and June 25, 2008.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-24, 27, 29 and 77-82 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a tautomer, a stereoisomer, a mixture of stereoisomers, a racemic mixture or a pharmaceutically acceptable salt of a compound of formula (1), does not reasonably provide enablement for a solvate of a compound of formula (1). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Factors to be considered in making an enablement rejection are summarized as:

- a) the quantity of experimentation necessary,
- b) the amount of direction or guidance presented,
- c) the presence or absence of working examples,
- d) the nature of the invention,
- e) the state of the prior art,
- f) the relative skill of those in the art,

g) the predictability or unpredictability of the art, and

h) the breadth of the claims.

In re Colianni, 195 USPQ 150 (CCPA 1977). In re Rainer, et al., 146 USPQ 218 (CCPA 1965). *Ex parte Formal*, 230 USPQ 546 (BPAI 1986).

a) Determining if a particular compound would form a solvate, or hydrate, would require synthesis and recrystallization of the compound solvate or hydrate using a variety of solvents, temperatures and humidities. The experimentation for solvates or hydrates is potentially open-ended.

b) The specification merely mentions the Applicant's intention to make solvates, without teaching the preparation thereof.

c) While the claims recite solvates, no working examples show their formation. As stated in Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190, 1194 (Fed.Cir. 1993):

The specification purports to teach, with over fifty examples, the preparation of the claimed compounds ... However ... there is no evidence that such compounds exist ... [T]he examples ... do not produce the postulated compounds ... [T]here is ... no evidence that such compounds even exist.

The specification shows no evidence of the formation and actual existence of solvates. Hence, Applicant must show formation of solvates or limit the claims accordingly.

d) The nature of the invention is chemical synthesis of solvates, which involves chemical reactions.

e) The state of the art recognizes that the formation, composition and therapeutic activity of solvates are unpredictable. The Federal Circuit has recognized a solvate as an example of a polymorph or pseudopolymorph (emphasis added):

"Polymorphs" are distinct crystalline structures containing the same molecules. These structural differences can affect various properties of the crystals, such as melting points and hardness (e.g., graphite and

diamonds are both crystalline forms of carbon)
.... [P]seudopolymorphs are often loosely
called polymorphs ... Pseudopolymorphs not only
have their molecules arranged differently but
also have a slightly different molecular
composition. A common type of pseudopolymorph
is a solvate, which is a crystal in which the
molecules defining the crystal structure "trap"
molecules of a solvent. The crystal molecules
and the solvent molecules then bond to form an
altered crystalline structure.

SmithKline Beecham Corp. v. Apotex Corp., 74 USPQ2d

1398, 1409 (Fed.Cir. 2005). The same rationale obtains
for hydrates; solvates in which the solvent is water.

Souillac, et al., Characterization of Delivery Systems,
Differential Scanning Calorimetry, pages 217-218 (in
Encyclopedia of Controlled Drug Delivery, 1999, John
Wiley & Sons, pages 212-227), recognize that different
polymorphs of the same drug can have different

therapeutic activity (emphasis added):

Because different polymorphic forms of the same
drug exhibit significant differences in their
physical characteristics, therapeutic activity
from one form to another may be different.
Studying the polymorphism of a drug and the
relative stability of the different polymorphs
is a critical part of pre-formulation
development.

Further, Vippagunta et al. (Advanced Drug Delivery Reviews, 48 (2001), pages 3-26) state "Predicting the formation of solvates or hydrates of a compound and the number of molecules of water or solvent incorporated in to the crystal lattice of a compound is complex and difficult." See page 18, section 3.4.

f) The artisan using Applicant's disclosure to prepare the claimed solvates and hydrates would be, e.g., an experienced process chemist with at least a BS chemistry degree.

g) Chemical reactions are known as unpredictable. In re Marzocchi, et al., 169 USPQ 367, 370 (CCPA 1971); In re Fisher, 166 USPQ 18, 24 (CCPA 1970). See above regarding the unpredictability of solvate and hydrate formation.

h) The breadth of the claims includes thousands of compounds of the instant formula (1) as well as presently unknown compounds embraced by the terms solvates and hydrates. See MPEP 2164.01(a), discussed

supra, justifying the conclusion of lack of enablement commensurate with the claims. Undue experimentation will be required to practice Applicant's claimed invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-24, 27, 29 and 78-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1, 2, 15, 23, 24, 27, 29 there is a valence problem when any of R^1 , R^2 and R^3 represents a sulfonyl, which is divalent, when a monovalent substituent is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 23 is rejected under 35 U.S.C. 102(a) as being anticipated by CA Registry No. 385424-29-3 {indexed in the Registry file on STN January 22, 2002}

The compound of CA Registry No. 385424-29-3 is embraced by the instant claimed invention. Therefore, the cited prior art anticipates the instant claimed invention.

Claims 1-9, 12-16, 18, 21-23, 77 and 78 are rejected under 35 U.S.C. 102(b) as being anticipated by:

- a) the compound of CA Registry No. 302575-58-2 {indexed in the Registry file on STN November 13, 2000};
- b) Gour et al. {WO 2001/053331} - see Compound 266 in Figure 15BD (Sheet 90/201) and page 7 of the specification;
- c) Niimura {JP 52-108427} - see the compound on page 139, top of second column;
- d) Gorbulenko et al. {CA 122:290759, 1995} - see, for example, the compound of CA Registry No. 136507-02-3;
- e) Nawwar et al. {CA 120:164052, 1994} - see the compound of CA Registry No. 153259-09-7;
- f) Moharram et al. {CA 101:151788, 1984} - see the compound of CA Registry No. 51864-18-7;

g) Jayanth et al. {CA 80:108415, 1974} - see, for example, the compound of CA Registry No. 40142-85-6; or

h) Dawood et al. {Journal of Chemical Research, Synopses, (1998), Vol. 4, pages 208-209} - see, for example, Compound 3 on page 208.

Each of the above cited prior art disclose at least one compound that is embraced by the instant claimed invention. Therefore, the instant claimed invention is anticipated by each of the above cite prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (571) 272-0710. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (571) 272-0699.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private

PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

The Official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

/Laura L. Stockton/
Laura L. Stockton
Primary Examiner, Art Unit 1626
Work Group 1620
Technology Center 1600

November 27, 2008